PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCH	\mathbf{HNG}	AI.	ITH	ORITY
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To: NOTIFICATION OF TRANSMITTAL OF BOULT WADE TENNANT THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL Attn. Thomson, Neil David Verulam Gardens SEARCHING AUTHORITY, OR THE DECLARATION 70 Gray's Inn Roaf RECEIVED London WC1X 8BT UNITED KINGDOM 3 1 AUG 2004 (PCT Rule 44.1) **BOULT WADE** Date of mailing (day/month/year) <u>TENNANT</u> 30/08/2004 Applicant's or agent's file reference FOR FURTHER ACTION P61329W000 See paragraphs 1 and 4 below International application No. International filing date (day/month/year) PCT/GB2004/002315 01/06/2004 Applicant BESPAK PLC

1. X	The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.							
	Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46): When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.							
	Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Fascimile No.: (41–22) 740.14.35							
1	For more detailed instructions, see the notes on the accompanying sheet.							
2.	The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.							
3.	With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:							
	The state of the s							
	the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.							
	no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.							
4. Rem	inders							
appli	tly after the expiration of 18 months from the priority date, the international application will be published by the national Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international cation, or of the priority claim, must reach the International Bureau as provided in Rules 90 <i>bis</i> .1 and 90 <i>bis</i> .3, respectively, re the completion of the technical preparations for International publication.							
inter	applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the national Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an national preliminary examination report has been or is to be established. These comments would also be made available to public but not before the expiration of 30 months from the priority date.							
date	in 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary nination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed for entry into the national phase before those designated Offices.							

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentiaan 2

NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,

Guide, Volume II, National Chapters and the WIPO Internet site.

_ Fax: (+31-70) 340-3016

Authorized officer

Vera Eberhardt

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 45.2).

Where a demand for international preliminary examination has been is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

Notes to Form PCT/ISA/220 (first sheet) (January 1994)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER							
P61329WO00	ACTION as w	see Form PCT/ISA/220 ell as, where applicable, item 5 below.						
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)						
PCT/GB2004/002315	01/06/2004	16/10/2003						
Applicant								
BESPAK PLC								
This International Search Report has been according to Article 18. A copy is being tra	prepared by this International Searching Aunsmitted to the International Bureau.	uthority and is transmitted to the applicant						
This International Search Report consists	of a total of sheets.							
X It is also accompanied by	a copy of each prior art document cited in th	is report.						
Basis of the report a. With regard to the language, the in	nternational search was carried out on the b	asis of the international anglication in the						
language in which it was filed, unle	ess otherwise indicated under this item.	asso or are international application in the						
The international s this Authority (Rule	search was carried out on the basis of a transe 23.1(b)).	station of the international application furnished to						
b. With regard to any nucleo	tide and/or amino acid sequence disclose	d in the international application, see Box No. I.						
2. Certain claims were foun	d unsearchable (See Box II).							
3. Unity of invention is lack	ing (see Box III).							
4. With regard to the title,								
X the text is approved as sub	mitted by the applicant.							
the text has been establish	ed by this Authority to read as follows:							
		:						
5. With regard to the abstract,								
the text is approved as sub	mitted by the applicant,							
X the text has been established	ed, according to Rule 38.2(b), by this Author	ity as it appears in Box No. IV. The applicant						
the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.								
6. With regards to the drawings,								
a. the figure of the drawings to be put	a. the figure of the drawings to be published with the abstract is Figure No1							
X as suggested by the								
	Authority, because the applicant failed to su							
b. none of the figures is to be	Authority, because this figure better characte	erizes the Invention.						
L of the lightes is to be	paonisieu with the abstract.							

International application No.

INTERNATIONAL SEARCH REPORT

PCT/GB2004/002315

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A dispenser (1) comprising a housing (3), a pressure sensor (22), processing means (23) and a display means (27), the housing being shaped for receiving, in use, a dispensing container (5) of the type containing medicament and having valve means for dispensing the medicament in metered volume doses, wherein, in use, the pressure sensor is capable of detecting a pressure signature produced on dispensation of medicament from the dispensing container, wherein the pressure sensor is operatively connected to the processing means for relaying signals indicative of the pressure signature for processing by the processing means, the processing means being programmed to analyse said signals and compare said signals against one or more data sets containing data indicative of one or more control pressure signatures, the processing means being programmed to use a result of said comparison to detect the quantity of medicament dispensed compared to an intended volume of the metered dose volume.

INTERNATIONAL SEARCH REPORT

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International Application No PCT/GR2004/00231

PCT/GB2004/002315 CLASSIFICATION OF SUBJECT MATTER PC 7 A61M15/00 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61M Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ C. DOCUMENTS CONSIDERED TO BE RELEVANT Category ° Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. χ US 6 390 088 B1 (NOEHL KLAUS ET AL) 1-32 21 May 2002 (2002-05-21) column 1, line 56 -column 3, line 21 column 4, line 47 -column 5, line 10 column 5, line 62 -column 7, line 37 figures X WO 95/07723 A (MEDTRAC TECH INC) 1 - 3223 March 1995 (1995-03-23) the whole document Α WO 02/058771 A (BACON RAYMOND J) 1 - 321 August 2002 (2002-08-01) page 4, line 20 -page 6, line 2 figures 1,2 -/--Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents : 'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance invention "E" earlier document but published on or after the international 'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone filing date 'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) 'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docu-ments, such combination being obvious to a person skilled in the ord. *O* document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed in the art. "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 18 August 2004 30/08/2004 Name and mailing address of the ISA **Authorized officer** European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo ni, Fax: (+31-70) 340-3016 Azaïzia. M

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INTERNATIONAL SEARCH REPORT

International Application No PCT/GB2004/002315

C (O1)-		PC1/GB2004,	7002315
Category *	ation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Odlegory	Citation of document, with indication, where appropriate, of the relevant passages	P	elevant to claim No.
A	US 6 138 669 A (ROSSITER DANIEL J ET AL) 31 October 2000 (2000-10-31) column 4, line 46 -column 5, line 37 column 6, line 20 -column 7, line 25 column 7, line 62 -column 8, line 10 figures 1-4		1-32
A	US 2003/052196 A1 (FUCHS KARL-HEINZ) 20 March 2003 (2003-03-20) the whole document		1-32
A	US 2003/075171 A1 (JONES ANTHONY PATRICK ET AL) 24 April 2003 (2003-04-24) page 1, paragraph 12 page 2, paragraphs 23-28 page 2, paragraph 36 -page 3, paragraph 45 figures		1-32
	WO 00/12162 A (BONNEY STANLEY GEORGE; JONES ANTHONY PATRICK (GB); GLAXO GROUP LTD) 9 March 2000 (2000-03-09) page 6, line 10-12 page 7, line 25 -page 10, line 13 figures 1-5		1-32

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No PCT/GB2004/002315

	atent document d in search report		Publication date		Patent family member(s)	Publication date
US	6390088	B1	21-05-2002	DE	4422710 C1	14-09-1995
				ΑT	192659 T	15-05-2000
	•			ΑU	701504 B2	28-01-1999
				AU	2886795 A	25-01-1996
				BR	9508137 A	04-11-1997
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				MO	9600595 A1	11-01-1996
				EP	0767683 A1	16-04-1997
				ES	2145281 T3	01-07-2000
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WO	02058771	Α	01-08-2002	ΕP	1357965 A1	05-11-2003
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						15-04-2004
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				ΑU	2068897 A	01-10-1997
				WO	9733640 A1	18-09-1997
US	2003052196	A1	20-03-2003	DE	10146815 A1	22 05 2002
		•••	20 00 2000	EP	1293224 A2	22-05-2003
				JP		19-03-2003
					2003111844 A	15-04-2003
US :	2003075171	A1	24-04-2003	AU	5031601 A	27-08-2001
				WO	0160438 A2	23-08-2001
				EP	1255580 A2	13-11-2002
				ĴΡ	2003522610 T	29-07-2003
						43 <u>-</u> 0/-2003
WO (0012162	Α	09-03-2000	AU	5970899 A	21-03-2000
				WO	0012162 A1	09-03-2000
				ΕP	1107810 A1	20-06-2001
				ĴΡ	2002523190 T	30-07-2002
				US	6651651 B1	25-11-2003

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY WRITTEN OPINION OF THE see form PCT/ISA/220 INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet) Applicant's or agent's file reference FOR FURTHER ACTION see form PCT/ISA/220 See paragraph 2 below International application No. International filing date (day/month/year) Priority date (day/month/year) PCT/GB2004/002315 01.06.2004 16.10.2003 International Patent Classification (IPC) or both national classification and IPC A61M15/00 Applicant **BESPAK PLC** This opinion contains indications relating to the following items: Box No. I Basis of the opinion ☑ Box No. II Priority Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. IV Lack of unity of invention Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement ☐ Box No. VI Certain documents cited Box No. VII Certain defects in the international application ☐ Box No. VIII Certain observations on the international application **FURTHER ACTION** If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220. For further details, see notes to Form PCT/ISA/220. Name and mailing address of the ISA:

European

European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 Authorized Officer

Azaïzia, M

Telephone No. +49 89 2399-6960



WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

10/575866

International application No. PCT/GB2004/002315

(AP20 Rec'd GTFTO 17 APR 2006

	Box N	No. I	Basis of the opinion
1.	With r	egard	to the language, this opinion has been established on the basis of the international application in the internation in the intern
	□ T	his op	pinion has been established on the basis of a translation from the original language into the following ye , which is the language of a translation furnished for the purposes of international search Rules 12.3 and 23.1(b)).
2.	With reneces	egard sary t	to any nucleotide and/or amino acid sequence disclosed in the international application and of the claimed invention, this opinion has been established on the basis of:
	a. type	of m	aterial:
		a se	quence listing
		table	e(s) related to the sequence listing
	b. form	nat of	material:
		in w	ritten format
		in co	mputer readable form
	c. time	of fili	ng/furnishing:
		conta	ained in the international application as filed.
		filed	together with the international application in computer readable form.
		furnis	shed subsequently to this Authority for the purposes of search.
3.	ha: co	pies is	on, in the case that more than one version or copy of a sequence listing and/or table relating thereto in filed or furnished, the required statements that the information in the subsequent or additional dentical to that in the application as filed or does not go beyond the application as filed, as ate, were furnished.
4.	Additio	nal co	mments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/GB2004/002315

-	Во	x No. II	Priority	·						
1	The following document has not been furnished:									
	copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).									
	translation of the earlier application whose priority has been claimed (Rule 43 <i>bis</i> .1 and 66.7(b))									
	Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.									
2.	This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.									
3.	Add	ditional d	bservations, if nec	essary:						
	Box	x No. V	Reasoned state	ment une	lor Pulo 42	this 1/aVI) with an and the second				
_			pplicability; citati	ons and	explanatio	Sbis.1(a)(i) with regard to novelty, inventive step or ns supporting such statement				
1.	Stat	tement								
	Nov	elty (N)		Yes: No:	Claims Claims	10-14, 17, 18, 22-29 1-9, 15, 16, 19, 20, 21, 30-32				
	Inve	entive ste	ep (IS)		Claims					
				No:	Claims	10-14, 17, 18, 22-29				
	Indu	istrial ap	plicability (IA)	Yes: No:	Claims Claims	1-32				
2.	Cita	tions and	d explanations							
	see	separat	e sheet							
	Вох	No. VII	Certain defects	in the int	ernational	application				
The	e follo	owing de				rnational application have been noted:				

see separate sheet

10/575866 AP20 Rec'd PCT/PTO 17 APR 2006

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

PCT/GB04/02315

International application No.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-B1-6 390 088 (NOEHL KLAUS ET AL) 21 May 2002 (2002-05-21)

D2: WO-A-95/07723 (MEDTRAC TECH INC) 23 March 1995 (1995-03-23)

- 2. Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. In fact, the embodiments of the invention described on page 5 ("... flow sensor ..." cf. lines 26-28) do not fall within the scope of the independent claim 1 ("A dispenser comprising ... a pressure sensor ..."). This inconsistency between the independent claim 1 and the description leads to doubt concerning the matter for which protection is sought, thereby rendering the claim unclear (Article 6 PCT).
- 2.1 For the purpose of the present written opinion and since it is clear from the description that flow sensors are also intended for use in a dispenser according to the present invention, the expression "a pressure sensor" used in the claims has been interpreted as directed to any kind of sensor having a proportional output signal.
- 3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
- 3.1 The document D1 discloses (the references in parentheses applying to this document) a dispenser ("inhaler 1" shown in fig.1) comprising:
 - a housing ("housing" cf c.5, l.64), **a sensor** ("first thermal sensor 5"), processing means ("electronic modul 3") and a display means ("optical display unit 34"), the housing being shaped for receiving, in use, a dispensing container ("supply container 2") of the type containing medicament and having valve means for dispensing the medicament in metered volume doses, wherein, in use
 - **the sensor** ("first thermal sensor 5") is capable of detecting **a signature** ("temperature profile" cf. c.3, l.4) produced in dispensation of medicament from the dispensing container (cf. c.1, l.64 to c.2, l.4), wherein **the sensor** ("first thermal sensor 5") is operatively connected to the processing means ("electronic modul 3")

for relaying signals indicative of **the signature** for processing by the processing means (cf. c.1, l.56 to i.63),

- the processing means ("electronic modul 3") being programmed to analyse said signals and compare said signals against one or more data sets containing data indicative of one or more **control signatures**, the processing means being programmed to use the result of said comparison to detect the quantity of medicament dispensed compared to an intended volume of the metered dose volume (cf. c.2, l.40 to l.58).
- 3.2 The document D2 discloses (the references in parentheses applying to this document) a dispenser ("electronic inhalant device 100" shown in fig.1) comprising: a housing ("body housing 120"), a sensor ("main sensing element 425" cf. p.15, l.36 to p.16, l.12 fig. 4), processing means ("electronic assembly 400" shown in fig. 4) and a display means ("LCD 1135" shown in fig.11), the housing being shaped for receiving, in use, a dispensing container ("canister package 215" shown in fig.2) of the type containing medicament and having valve means for dispensing the medicament in metered volume doses, wherein, in use
 - **the sensor** ("main sensing element 425") is capable of detecting **a signature** produced in dispensation of medicament from the dispensing container (cf. p.15, l.36 to p.16, l.12), wherein **the sensor** is operatively connected to the processing means ("electronic assembly 400") for relaying signals indicative of **the signature** for processing by the processing means (cf. p.16, l.25 to p.17, l.7 fig.8),
 - the processing means ("electronic assembly 400") being programmed to analyse said signals and compare said signals against one or more data sets containing data indicative of one or more **control signatures**, the processing means being programmed to use the result of said comparison to **implicitly** detect the quantity of medicament dispensed compared to an intended volume of the metered dose volume (cf. p.18, l.8 to p.19, l.1 fig.8).

The subject-matter of independent claim 1 is therefore not new (Article 33(2) PCT).

4. The additional features of dependent claims 2-32 are EITHER already known from D1 and/or D2, OR define slight constructional changes in the dispenser which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently,

dependent claims 2-32 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT) and/or inventive step (Article 33(3) PCT).

5. The subject-matter of claims 1-32 is considered industrially applicable since it can be made or used in any kind of industry (Article 33(4) PCT).

Re Item VII

Certain defects in the international application (form and content)

- 6. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.
- 7. The independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, with those features known in combination from the prior art (documents D1 and/or D2) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 8. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).